temperature and for over three months at 104 °F. This durability is enhanced when the assay tests are stored in the delivery systems of the present invention. For example, in some embodiments, assay tests enclosed in a delivery system remain functional for over two years.

Certain illustrative chemistries for use at the reaction site are provides below. The exemplary chemistries are not intended to limit the scope of the invention. In one embodiment of the present invention, the chemicals used at the reaction site are prepared in several submixes prior to combination and application on the desired solid support (*e.g.*, test strip). The first submix comprises water (RO/DI water) (0.48 kg), dextran (40.0 g), starch (7.50 g), and gelatin (6.25 g). The water is added to a suitably sized vessel, followed by addition, with stirring, of dextran, starch, and gelatin. The components are stirred until homogenous (of even appearance). The solution will be milky in appearance. After the solution is homogenous, the mixture is heated to boiling (100°C) for three minutes after the mix turns clear. The mixture is then cooled with stirring (ice should not be used). The mixture may become slightly cloudy after cooling.

The second submix comprises water (RO/DI water) (240 g), potassium EDTA (120 mg), citric acid (11.53 g), and potassium iodide (12.5 g), L-Cysteine, and sodium nitrite (the amounts of L-Cysteine and sodium nitrite are dependent on the activity of the alcohol oxidase). L-Cysteine and sodium nitrite may be used at 290 mg/L and 130 mg/L respectively. However, to achieve maximal results, multiple concentrations should be made that are, for example, 10% higher and lower in concentration of L-Cysteine and sodium nitrite, where each concentration is tested against the specific enzyme lot to be used to determine the best concentration for use with the particular enzyme lot. A desired concentration provides an accurate, reliable, and detectable readout. For example, a desired concentration provides minimal false negative and false positives. In preferred embodiments, where the test is to detected an alcohol concentration of 0.04%, there are not false positives when a 0.000 control is used, no more than 15% false positives when 0.016 is used, and no more than 0.01% false negative results when 0.064 is used. The water is added to a suitably sized vessel,

followed by addition, with stirring, of the potassium EDTA, L-Cysteine, and citric acid until completely dissolved. The pH of the mixture is adjusted to approximately 6.4 (*e.g.*, using sodium hydroxide and HCl as necessary). Once the pH is adjusted, sodium nitrite and potassium iodide are added and the mixture is stirred until everything is dissolved. The solution should be clear in color.

The third submix comprises water (RO/DI water) (20 g), sodium phosphate, dibasic, heptahydrate (134 mg), alcohol oxidase (80 KU), peroxidase (48 KU), catalase (45 KU), and STABILGUARD (130 ml) (SurModics, Inc., Eden Prairie, MN). The water is added to a suitably sized vessel, followed by addition, with stirring, of the sodium phosphate dibasic, heptahydrate. The pH of the solution is adjusted to approximately 7.0. While gently stirring the phosphate buffer solution, the peroxidase is added and slowly stirred until it is dissolved (approximately 10 minutes). This solution is the peroxidase mixture. In a separate vessel, the alcohol oxidase is added and slowly stirred while the peroxidase mixture is added. Next, the catalase and STABILGUARD are added. The mixture is gently stirred for approximately 30 minutes. The solution should be a clear, cherry color.

In a vessel large enough to hold all three submixes, the submixed are added together and stirred until completely mixed. Lactitol (50 g) is added and thoroughly mixed until dissolved. The solution should be yellow and slightly cloudy. The solution is then mixed gently at room temperature for 90 minutes as an incubation period. The solution should be used within 6 hours of preparation. To use, the solution is applied to a desired test assay (*e.g.*, applied to an absorptive material on a test strip). For example, the reaction mixture may be applied to a thin strip of filter paper and dried (160°F) to create a test strip. Application and drying are preferably conducted in a low humidity environment (e.g., ambient humidity of less than 5%, preferably less than 3%, and most preferably less than 2%) to facilitate fast drying and maintain optimal reactivity and performance of the assay tests. In some preferred embodiments, all manufacturing steps are carried out in a low humidity environment. In some embodiments, formulations are made as above, but without catalase, nitrite, or citrate.

Each of the components present on the test strip are non-toxic and non-carcinogenic. Each are found as food ingredients, approved food additives or substances normally encountered in the diet or produced normally in the body. Amounts present in the testing pad (e.g., 133 micrograms of potassium iodide, 0.2 micrograms of sodium nitrite, 1.3 micrograms of EDTA, sodium salt, 4.7 micrograms of cysteine, 123 micrograms of citric acid, 533 micrograms lactitol, and 0.6 micrograms disodium phosphate), only a portion of which would be solubilized and ingested, represent small fractions of the amounts encountered in the daily diet and from other sources such as in pharmaceutical products.

This reaction site provides a stable, accurate, inexpensive, non-toxic, non-irritant, non-carcinogenic on/off chemistry for use in alcohol detection. The reaction time is less than two minutes and remains positive for at least twenty additional minutes.

B) Glucose

The present invention provides non-invasive glucose tests. For example, the present invention provides oral glucose tests for monitoring glucose levels from saliva. The glucose levels in saliva correlate with blood glucose levels and can be used, whether quantitative or qualitative, in the management of diabetes. Currently four billion dollars a year is spent on glucose testing for diabetics throughout the world. It is estimated that there are 16 million diabetics in the United States and many more throughout the world. However, only 8 million of the diabetics in the United States have been diagnosed with the disease. Approximately 7 million of these diagnosed individuals are Type 2 diabetes and 1 million are Type 1 diabetes. Type 1 diabetics must constantly measure and manage their glucose levels and must take insulin. Failure to correctly manage glucose levels in both Type 1 and Type 2 diabetics could result in death. However, such negative consequences are more likely and occur faster in Type 1 diabetics.

Current accurate products for measuring glucose levels involved taking a blood sample (e.g., pricking a finger) and having blood glucose measured using a portable